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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,840	09/13/2000	Paul Remijan	2476.1003-001	7821

30407 7590 05/10/2007
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EXAMINER

LEUBECKER, JOHN P

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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05/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/660,840

Applicant(s)

REMIJAN ET AL.

Examiner

John P. Leubecker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 19-21, 34, 40-50, 52-58 and 70-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 22-33, 35-39, 51, 59-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 13, 2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7, 8, 9, 15, 16, 24, 27, 36, 38, 51, 60, 65, 67 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 7-9, term “the light absorbing layer” lacks antecedent basis.

As to claims 15 and 16, term “the optical element” lacks antecedent basis.

As to claim 24, recitation of an “optical coupler that connects a light source to the optical waveguide” is indefinite in scope with respect to the currently claimed combination that includes an illumination channel concentric about the optical waveguide. It appears that claim 24 was amended on December 5, 2005 to be directed to structure of a mutually exclusive and distinct species (combined illumination and imaging channel) that was not elected in the requirement made on November 19, 2002. Since this claim was originally directed to the elected species, and was erroneously not withdrawn after being amended, Applicant is given this opportunity to

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amend this claim to be consistent with the elected species currently being examined (which will overcome the current 112 rejection). Failure to do so will result in the withdrawal of this claim.

As to claim 27, recitation of an “a light source that is optically coupled to the optical waveguide” is indefinite in scope with respect to the currently claimed combination that includes an illumination channel concentric about the optical waveguide. It appears that claim 27 was directed to structure of a mutually exclusive and distinct species (combined illumination and imaging channel) that was not elected in the requirement made on November 19, 2002. Since this claim was erroneously not withdrawn and examined, Applicant is given this opportunity to amend this claim to be consistent with the elected species currently being examined (which will overcome the current 112 rejection). Failure to do so will result in the withdrawal of this claim.

As to claims 36 and 38, terms “the first layer” and “the second layer” lack antecedent basis.

As to claim 51, the phrase “such that the illumination waveguide is optically coupled to the imaging device” is ambiguous since this structure is not consistent with Applicant’s invention (and not disclosed in the disclosure). It appears that it should read “such that the *imaging channel* is optically coupled to the imaging device”.

As to claim 60, since “waveguide” is now referring to the “illumination waveguide” in claim 51, recitation of a “fiber optic illumination channel around the [illumination] waveguide” is indefinite as to scope of the claim. If Applicant intended to recite this combination, there would be 112, first paragraph issues as lacking support in the specification.

As to claim 65, recitation of a “distal optical system” wherein a “lens at a distal end of the imaging channel” has previously been claimed (claim 51) begs the question: are two different

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distal optical systems being claimed? For the purposes of applying prior art, they will be considered as being the same.

As to claim 67, recitation of a “lens assembly” wherein a “lens at a distal end of the imaging channel” has previously been claimed (claim 51) begs the question: are two different lens assemblies being claimed? For the purposes of applying prior art, they will be considered as being the same.

As to claim 68, recitation of a “illumination channel” wherein a “illumination waveguide” has previously been claimed (claim 51) begs the question: are two different illumination channels being claimed? For the purposes of applying prior art, they will be considered as being the same.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5, 6, 9, 12, 15, 17, 18, 22-26, 28-31, 33, 35, 39, 51 and 59-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. (U.S. Pat. 5,423,312) in view of Allred, III (U.S. Pat. 4,854,302) and further in view of Kurtzer (U.S. Pat. 5,168,863).

As to claims 1, 28 and 51¹, Siegmund et al. discloses a optical waveguide (1) having a light absorbing layer (7), a concentric illumination channel (25), a handle (3,27) attached to the optical waveguide, an optical lens element (5) coupled to the distal end of the waveguide, an optical relay (17) mounted in the handle (Fig.1) and optically coupled to a proximal end of the waveguide, and an imaging device (CCD camera) mounted in the handle at a proximal end of the optical relay. Siegmund et al. fails to specify the length and diameter of optical waveguide. However, analogous miniature endoscopes (note Allred, III, Figure 2, col. 4, lines 28-34) are known to include an optical waveguide with a diameter of 2 mm or less and a length of somewhere between 3.3 cm and 11 cm². Since Siegmund et al. fails to teach any particular length and diameter, it would have been obvious to one of ordinary skill in the art to have made the waveguide any desired diameter and length to meet the particular requirements for a certain procedure, and specifically, any length and diameter contemplated in the prior art, since such contemplation suggests a particular need or use for those dimensions in the prior art.

Furthermore, Siegmund et al. fails to disclose a sterile disposable sheath attached to the probe and extending over the handle. However, Kurtzer teaches an analogous endoscope having such sheath (20). It would have been obvious to one of ordinary skill in the art to have provided a sheath over the handle of Siegmund et al. to provide a sterile barrier between the handle/camera and the patient to protect the patient from any contamination from elements of the device which are normally handle by the surgeon and to protect the handle/camera from contamination from the patient (e.g., fluids, bacteria).

¹ Assuming that claim 51 is to be corrected as suggested above in the rejections under 35 USC 112, second paragraph.

Clearly a diameter of less than 2 mm, as taught by Allred, III would encompass the diameters of claims 2 and 3. As to claim 5, 6, 30 and 31, the waveguide of Siegmund et al. comprises a high-index glass rod of a refractive index greater than 1 (which includes 1.6). As to claim 9, note col.4, lines 3-8. As to claims 12, note outer sheath (37). As to claims 18 and 65, the insertion section as describe above would form a needle, as broadly as claimed. As to claims 17 and 22, an image from a CCD camera is inherently viewed on a display. As to claims 23 and 36, note that optical fibers (25) are optically coupled to a light source in the handle (note coupling point 43) via fiber optic connector (41). As to claim 24, note coupling 39. As to claim 59, note optical fibers (41). As to claim 60, note ring of optical fibers (25) (assuming that illumination channel and waveguide are referring to the same thing). As to claims 61 and 62, note col.4, line 27. As to claim 66, note col.4, lines 47-52 as to the cannula. As to claims 67 and 68, note col.6, lines 17-26 regarding a locking mechanism (70).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III and Kurtzer, as described above, and further in view of Woodard et al. (U.S. Pat. 5,947,958).

Although the different distal tip configurations (71,72, Figs. 8b,8c) of Siegmund et al. provide dispersive properties and could be considered as a “ring”, Woodard et al. explicitly teach that, in an alternative to forming the tip, that other dispersive elements including lenses and refractive gradients could be used (col.5, lines 39-44). Thus, it would be obvious to one of

² The probe sleeve (18) is about 3.3 cm in length and the main housing (12) about 7.5 cm in length. Since the optical waveguide (24) extends slightly into the main housing (note proximal end 42, Fig.2), it would have a length of somewhere between 3.3cm and the overall length of about 11 cm.

ordinary skill in the art to have used a separate dispersive element in the device of Siegmund et al. as an obvious design alternative for dispersing the illumination light.

7. Claims 7, 10, 13, 14, 16 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III and Kurtzer.

As to claims 7 and 10, Siegmund et al. fails to specify the thickness of the light absorbing layer and the wall thickness of the illumination channel. However, inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thickness of these layers (Applicant discloses the claimed ranges simply as preferred), the choice of such thicknesses would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Since miniaturization is a key design consideration in the non-invasiveness of endoscopic devices and thicknesses in the claimed ranges are not extraordinary in the art, such claimed ranges would be considered obvious and desirable.

As to claim 13, Siegmund et al. explicitly teaches that the outer sheath can be made from metals or plastics (col.5, lines 2-3) but fails to specify polyamide. If not inherently encompassed by “plastics”, Siegmund’s teaching would prompt one of ordinary skill in the art to draw from common knowledge. Polyamide is a well known plastic material. It would therefore be obvious to one of ordinary skill in the art to have used polyamide. Evidence that polyamide is a well known plastic material will be provided only if Applicant disagrees on record to such notice.

As to claim 14, Siegmund et al. fails to mention the thickness of the outer sheath. However, inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thickness of the sheath (Applicant discloses the claimed ranges simply as preferred), the choice of such thickness would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Since miniaturization is a key design consideration in the non-invasiveness of endoscopic devices and the claimed is not extraordinary in the art, such claimed thickness would be considered obvious.

As to claim 16, Siegmund et al. fails to disclose the material of the lens. Both glass and plastic lenses are notoriously well known in the art. Either can be used for the same purposes and both have advantages and disadvantages. It would have been obvious to one of ordinary skill in the art to have used plastic for the material of the lens of Siegmund et al. as a matter of design choice.

As to claim 32, Siegmund et al. fails to disclose the specific properties of the high index of refraction glass rod (i.e., that it is an F2 or F7 glass). If not inherently encompassed by "high index of refraction glass", Siegmund's teaching would prompt one of ordinary skill in the art to draw from common knowledge. F2 and F7 glasses are well known types of glass. It would have therefore be obvious to one of ordinary skill in the art to have used well known types of glass such as F2 and F7 glass. Evidence that these are well known types of glass will be provided only if Applicant disagrees on record to such notice.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III and Kurtzer, as described above, and further in view of Eastman (U.S. Pat. 5,319,731).

Siegmund et al. disclose the device as described above wherein the light absorbing layer is a hydrogen-fired blackened surface and thus fails to disclose such layer as being comprised of extramural absorption glass. Since such extramural absorption glass is known to provide similar properties (e.g., attenuate stray light) (note Eastman, col.1, lines 46-65 and col.5, lines 35-53), it would have been obvious to the skilled artisan to have used extramural absorption glass for the absorption layer as an obvious design alternative. Use of such absorption glass would simplify the application of the absorbing layer by eliminating the hydrogen-firing process while still providing good image quality.

9. Claims 11 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III and Kurtzer, as described above, and further in view of Strack (U.S. Pat. 3,902,880).

Since Siegmund et al., as described above, does not mention any specific optical properties, one of ordinary skill in the art would draw from conventional knowledge in the art when reducing such device to practice. Strack evidences that illumination core materials can have a refractive index of 1.5 to 1.81 (col.3, lines 12-17) with the refractive index of the cladding being lower. The claimed ranges are inherent properties of typically known materials (e.g., glasses, plastics) that have been used for the same purposes (e.g., illumination). Clearly, such

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specific optical properties would be obvious to one of ordinary skill in the art as they are inherent in the materials that would conventionally be used.

10. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III and Kurtzer, as described above, and further in view of Kishi et al. (U.S. Pat. 4,972,827).

Although claim 69 further recites a “stylet” which could be anticipated by a cannula, it appears from the specification that Applicant is using the term “stylet” to define what is commonly referred to as an obturator. Kishi et al. shows what is conventionally known in the art: a cannula (trocar) which eventually receives the endoscope is inserted through tissue with the aid of an obturator (note col.1, lines 22-34). It would have been obvious to one of ordinary skill in the art to have provided a trocar/obturator with the Siegmund et al. device to aid in insertion of the endoscope into the body.

Response to Arguments

11. Applicant's arguments filed February 13, 2007 have been fully considered but they are not persuasive.

Although the Examiner takes the position that the previous rejection over Siegmund, Yoshida and Kurtzer is proper and maintainable, at least for independent claims 28 and 51, Allred III is being used in a substantially similar rejection to address the newly added limitation in claim 1 with respect to the length of the optical waveguide.

Regarding the Siegmund reference, Applicant distorts information regarding conventional endoscopes and for some reason expects the Examiner to translate such information as a limitation on the Siegmund device. With all due respect, the Examiner points out that Siegmund never once provides a dimension for the disclosed invention and never explicitly or even implicitly implies that the invention takes on the specific dimensions discussed with respect to the prior art (col.1, lines 33-36). In fact, Siegmund states that the prior art endoscopes have lengths that “reach *as high as* 30-40 centimeters”. This is the upper limit of a range and no lower limit is given. Thus, Siegmund does not even limit the prior art endoscopes to 30-40 centimeters.

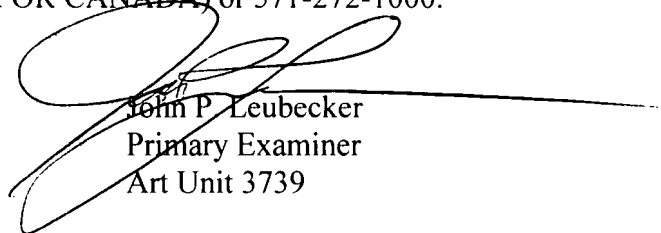
Again Applicant argues that it would not be obvious to “add the features of the larger system in Siegmund or Kurtzer, for example, in a small diameter device” (the small diameter device being Yoshida. Although a different reference is now being relied upon instead of Yoshida, the Examiner fears that such misunderstanding of the previous rejection will occur again and thus the Examiner will try to explain the concept of an obvious rejection once again. In the previous rejection, the Examiner does NOT combine any features with Yoshida. Instead, a teaching from Yoshida is used to show the level of ordinary skill when contemplating a diameter for the endoscope of Siegmund et al. This same concept now occurs with the Siegmund and Allred III references. Thus, Applicant would have to successfully argue why, given the disclosure of the Siegmund device and the lack on any specific dimensions for such device, it would not be obvious to one of ordinary skill in the art to make the device with any preferred dimension, and specifically dimensions known to be used in the art, as now being proposed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



John P. Leubecker
Primary Examiner
Art Unit 3739

jpl